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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/614,790	07/12/00	KLEYNE	S HME/7982.001

HM12/0517  
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EXAMINER

WILLIS, M

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/614,790	Applicant(s) KLEYNE, SHARON F.	
	Examiner Michael Willis	Art Unit 1619	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 20 March 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

Applicant's amendment of 20 March 2001 is acknowledged. Amended claims 1-23 and new claims 24-43 are pending. Applicant has amended independent claims 1, 15, and 19 to call for an aqueous fluid that consists essentially of water. New claims 24-27 are drawn to an aqueous fluid that is substantially free of preservatives. Applicant has also added claims 28-43, drawn to a method for moisturizing the aqueous layer of the tear film on the surface of the eye. It is noted that new claims 28-41 do not have the limitation of consisting essentially of water.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 1-22 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. Based on applicant's amendment, the rejection of claims 1-22 under 35 USC 112, second paragraph is withdrawn.

#### ***Claim Rejections - 35 USC § 102***

3. Claims 1-10 and 15-22 have been rejected under 35 U.S.C. 102(b) as being anticipated by Rocca et al (WO 96/00050) in view of Records, "The Tear Film," Chapter

3 of Volume 2 of Biomedical Foundations of Ophthalmology, Ed. William Tasman and Edward Jaeger, Lippincott Publishers.

4. Applicant has amended independent claims 1, 15, and 19 to call for an aqueous fluid that consists essentially of water. Applicant traverses the rejection on the grounds that Rocca does not disclose or suggest a method for moisturizing the eye in which an aqueous fluid consisting essentially of water is administered to the surface of the eye. Based on applicant's amendment, the rejection of claims 1-10 and 15-22 under 35 USC 102(b) is withdrawn.

5. Applicant's amendment necessitates the following new grounds of rejection: Claims 1-12, 15-18, 24-25, 28-39 and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Embleton et al (WO 97/23177). Embleton discloses ophthalmic treatment liquids such as artificial tears, dry eye therapies, comfort drops, or irrigation fluids with examples that include physiological saline or water (see page 12, lines 6-9; and page 13, lines 7-12). Embleton further discloses the use of smaller instilled volumes of eye drops for the surface of the eye than are normally delivered by most commercial ophthalmic droppers in order to minimize drainage loss and wastage (page 1, lines 5-23; and page 2, lines 16-27). Drainage loss is understood to mean runoff of the tear film from the eye. Embleton also discloses that ocular bioavailability of ophthalmologically active compounds can be enhanced by delivery to the surface of the eye in the form of a jet or stream of droplets (see page 2, lines 29-37; and page 3, lines 1-10). It is the position of the examiner that aqueous eye moisturizers are included within the class of

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ophthalmologically active compounds. Embleton discloses streams of droplets with diameters as low as 20 microns (see page 3, lines 11-29) and total volume of treatment fluid most preferably in the range from 3 to 8 microliters (page 3, lines 30-37). While the osmolarity of the treatment liquids is not disclosed, the osmolarity of water is inherently less than the osmolarity of the normal aqueous layer of the tear film. In disclosing the use of water, Embleton does not disclose the use of preservatives in the water (page 13, lines 7-12).

***Claim Rejections - 35 USC § 103***

6. Claims 1-23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Rocca et al (WO 96/00050) in view of Varma (U.S. Pat. 5,032,392).

7. Rocca teaches an ocular treatment device and methods for applying a treatment liquid to the eye. Varma teaches aqueous ophthalmic solutions for the treatment of dryness of the eyes. Applicant traverses the rejection on the grounds that neither Rocca nor Varma disclose nor suggest a method for moisturizing the eye in which an aqueous fluid consisting essentially of water is administered to the surface of the eye. Based on applicant's amendment, the rejection of claims 1-23 under 35 USC 103(a) is withdrawn.

8. Applicant's amendment necessitates the following new grounds of rejection:

Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Embleton et al (WO 97/23177) in view of Varma (US Pat. 5,032,392) and Rocca et al (WO 96/00050).

9. Embleton teaches a dosage of ophthalmic treatment liquid which takes the form of a jet or stream of droplets. The stream of droplets is aimed at the surface of the eye. The ophthalmic treatment liquids for use as artificial tears, dry eye therapies, comfort drops, and irrigation fluids include water or physiological saline (see page 12, lines 6-9; and page 13, lines 7-12). The stream of droplets is comprised of a smaller volume than normally delivered by previous commercial eye droppers in order to minimize drainage (page 1, lines 5-23; and page 2, lines 16-27). Drainage loss is understood to mean runoff of the tear film from the eye. Embleton teaches that delivery of a small volume of liquid in a stream of droplets is beneficial in and of itself in enhancing the delivery of ophthalmologically active compounds to the surface of the eye (see page 2, lines 29-37; and page 3, lines 1-10). It is the position of the examiner that aqueous eye moisturizers are included within the class of ophthalmologically active compounds. Embleton discloses streams of droplets with diameters as low as 20 microns (see page 3, lines 11-29) and total volume of treatment fluid most preferably in the range from 3 to 8 microliters (page 3, lines 30-37). While the osmolarity of the treatment liquids is not disclosed, the osmolarity of water is inherently less than the osmolarity of the normal aqueous layer of the tear film. Embleton does not teach the addition of preservatives to ophthalmic treatment liquids. The reference lacks an ophthalmic treatment kit and is silent with respect to the pH of the liquids.

10. Rocca teaches an ocular treatment device and methods for applying a treatment liquid to the eye (see page 15, claims 1-17). It is the position of the examiner that the device of Rocca meets the limitation of an ophthalmic treatment kit. Rocca teaches that

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by using a physical mechanism for generating the jets or droplets, there is no restriction on the nature of the liquid from which the droplets are formed (page 2, lines 22-34).

Rocca teaches that the disclosed device is particularly beneficial in ocular treatment with aqueous solutions because alternative devices using electrostatic charge are not compatible with aqueous solutions (page 2, lines 29-31).

11. Varma teaches aqueous ophthalmic solutions for the treatment of dryness of the eyes. Varma teaches that the pH of ophthalmic preparations is preferably within the range of from about 6.6 to about 7.8. Outside of this range, solutions have a tendency to cause irritation (see col. 4, lines 29-43).

12. It would have been obvious to one of ordinary skill at the time the invention was made to have modified the dosage forms of Embleton by including them in a kit as taught by Rocca in order to benefit from the particular suitability of Rocca's device with aqueous droplets and to vary the pH within the range taught by Varma in order to avoid irritation of the eyes.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Gilbard (US Pat. 4,775,531) discloses non-toxic ophthalmic preparations consisting essentially of water.


14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on M-F from 8:30 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose number is (703) 308-1234.

  
Michael A. Willis, Ph.D.  
Patent Examiner  
May 15, 2001

  
Michael Hartley  
Primary Examiner  
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